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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 24

Application Number: 09/489,982
Filing Date: January 21, 2000
Appellant(s): STOLL ET AL.

MAILED

JUL 07 2004

GROUP 3600

David E. Herron II
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 January 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

The addition of the issue of whether claims 1-21 are unpatentable under 35 USC

103(a) as obvious in view of Gombrich et al. (4,835,372) in view of Leigh-Spencer et al.

(5,602,802) and an article published by the Computer Science Telecommunication

Board National Research Council.

(7)   *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall

together is not agreed with because in the arguments within the brief it appears some of

the claims do stand or fall together. Thus, based on the arguments in the brief, the

pending claims are being constructively grouped as follows:

I) Grounds of rejection:	Goetz in view of an article by the Computer Science Telecommunications Board
Group I:	claims 1-21
II) Grounds of rejection:	Gombrich in view of Leigh-Spencer and an article by the Computer Science Telecommunications Board
Group I:	claims 1, 2-6, & 20
Group II:	claim 21
Group III:	claims 7 & 8-13
Group IV:	claims 14 & 15-18

(8)   *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9)   Prior Art of Record

4,835,372   *GOMBRICH ET AL.*   *5-1989*

5,602,802   *LEIGH-SPENCER ET AL.*   *2-1997*

6,397,190   *GOETZ*   *5-2002*

Computer Science and Telecommunications Board, For the Record, National Academy

Press, July 1997, pp. 12, 86-89, 106-108, and 120-122

(10)   Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(A) The rejections of claims 1-21 under 35 U.S.C. 112, first paragraph, as containing

subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention, are hereby withdrawn

due to the arguments presented in the brief filed 26 January 2004.

(B) Claims 1-21 are all rejected under 35 U.S.C 103(a). This rejection is set forth in the

prior Office Action, Paper No. 17, and reproduced hereinbelow. The rejections which

appear below substantially repeat the rejections made in the previous Office Action

(Paper No. 17). The text of those sections of Title 35 U.S. Code relied upon in the

Examiner's Answer is set forth in the previous Office Action, Paper No. 17.

1.   Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gombrich et al. (4,835,372) in view of Leigh-Spencer et al. (5,602,802), and the

Computer Science Telecommunication Board (For the Record Protecting Electronic

Health Information, Computer Science Telecommunication Board National Research

Council, National Academy Press, Washington, DC, July 1997).

(A) As per claim 1, 6, 11-12, Gombrich discloses a method for providing accurate

identification of a patient and for items relating to a patient such as drugs (col. 1 lines 9-

17 and col. 2 lines 36-45) comprising:

        (a) providing a portable handheld patient terminal (PHPT) with a bar code reader

to provide the main data collection component of patient identification information,

wherein the PHPT allows storage of data relating to patients in memory (reads on

"write"), wherein the PHPT utilizes infrared (IR) transmission/reception by an infrared

transmitter/receiver arrangement or interface to transmit or send data stored in memory

(reads on "read) (col. 3 line 59 to col. 4 line 20, col. 5 line 18 to col. 6 line 11, col. 10 line

57 to col. 11 line 5, col. 12 lines 14-66, col. 23 line 11-36);

        (b) receiving at the PHPT (also called the bar code reading device) prescription

information through the interface, wherein prescription information includes a

recommended dosage and time to administer drugs entered by a staff member,

secretary, or nurse (reads on "by a prescriber") (col. 15 line 51 to col. 16 line 17, col. 17

line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24);

(c) downloading from memory of the PHPT data via the communications port,

wherein the data includes drug information, such as drugs administered (col. 24 lines

11-36); and

(d) filling the prescriptions at a pharmacy (col. 14 line 65 to col. 15 line 48).

Gombrich fails to disclose transferring a carrier by a patient to a pharmacy and

downloading information *at the pharmacy*.

Leigh-Spencer includes a programmable reminder system for medications where

the prescribing pharmacist has the ability to program a simple portable module carried

by the patient, wherein the programming of the module occurs when the pharmacist is

filling a patient's prescription, wherein the patient carriers the module to the pharmacy,

and wherein a two-way communication link is provided between the portable module

and the programming station of the pharmacist (col. 3 lines 20-53, col. 2 lines 15-30,

and col. 8 lines 6-40 and).

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the aforementioned components of Leigh-Spencer

within the method of Gombrich with the motivation of providing an efficient and cost-

effective distribution of portable modules for use by patients and pharmacists (Leigh-

Spencer; col. 2 lines 40-50) and ensuring patient's receive quality care by ensuring

patient receive the proper prescription drugs at the proper time (Gombrich; col. 1 lines

47-60).

Gombrich does not expressly disclose the steps of "encrypting prescription data

defining a prescription so that the data would be indecipherable without appropriate

computer decryption software," "decrypting said prescription data from indecipherable form into a form that would be decipherable," and "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

However, Gombrich teaches providing for a security mechanism for prescription information. In particular, Gombrich includes providing limited access to Gombrich's system by logic means for verifying a user ID and patient ID checks and for providing an indication at a patient terminal means of the result of the verification (col. 2 lines 50-55, col. 46 lines 23-27).

Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (reads on "indecipherable without appropriate computer decryption software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the method taught collectively by Gombrich and Leigh-Spencer with the motivation of controlling the use of information in

order to protect the privacy of patients (Computer Science Telecommunication Board, pg. 12, 120) and providing limited access to a system (Gombrich; col. 2 lines 50-55).

As per the recitation of "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact," it is respectfully submitted that Gombrich teaches the input and output of data using infrared communication or RF communication (col. 10 line 57 to col. 11 line 51, col. 24 lines 11-36), wherein the RF signals allow for real time data transmission using an RF transceiver and antenna arrangement. The input and output of data using infrared or RF signals or infrared are wireless as evidenced by Gombrich (col. 23 15-20), and thus these wireless communication protocols are considered to be a form of "the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

(B) As per claim 2, Gombrich discloses entering an ID and password prior to accessing the PHPT to receive information at the PHPT (col. 16 lines 3-17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col. 40 line 2).

(C) As per claim 3, Gombrich discloses storing and displaying upon request six to ten previously recorded and administered PRN or other controlled drug administered and the times they were administered in the bar code reading device (col. 2 lines 41-45, col. 3 lines 10-18, col. 3 lines 47-53, col. 5 lines 36-48, col. 14 lines 40-64, col. 16 lines 49-

55, and col. 24 lines 11-36) and providing a green status light or other appropriate

indication on the LCD display of the bar code reading device when a drug is

administered and automatically recording the drug was administered, and pushing a

button on the bar code reading device if the treatment did not occur (col. 16 line 67 to

col. 17 line 29).

Gombrich is entirely silent as to operating a digital clock/calendar within the

carrier to generate internal values of time and date, providing the carrier with a

prescription compliance switch interfaced to the clock/calendar, and operating a

compliance switch by a patient upon taking a medication specified by the prescription.

Leigh-Spencer includes:

a clock within a portable module to program the current time of day and

the specific times for each alarm, wherein a set alarm module of the

programming station sets the portable module alarm times, wherein the set alarm

module has a number of doses command and time of dose command for

determining the portable module times (col. 2 lines 48-50, col. 8 lines 56-67, col.

10 lines 31-40 and 50-52, col. 11 lines 61-65, col. 13 lines 7-12);

a push button within the portable module, wherein a microprocessor is

provided for receiving and storing alarm information and for providing visual and

auditory alarms signals to a sound device and LED and for receiving an alarm

silence signal from the push button (Fig. 1 and 6A, col. 6 lines 17-40, col. 11 lines

14-35); and

providing an auditory alarm warning to a patient that it is time to take a

prescribed medicine, wherein the alarm is silenced by the patient by pushing the

push button (col. 3 lines 34-36, col. 5 lines 14-16, col. 10 line 66 to col. 11 line 3).

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the aforementioned features of Leigh-Spencer within

the method of Gombrich with the motivation of increasing the effectiveness of treatment

and reducing harm to a patient by providing a reminder device to ensure a patient

follows the administration instructions of medication, including the specific time of day

and dose of medication the patient should take (Leigh-Spencer; col. 1 lines 15-25).

(D) As per claim 4, Gombrich discloses providing an alert if a particular drug

administration is overdue and/or improper at a portable bar code reading device (col. 2

line 67 to col. 3 line 4 and col. 17 lines 37-59).

Gombrich fails to expressly disclose providing a carrier with an annunciator

element, entering into the carrier by the pharmacist, schedule data defining a

prescription schedule comprising a plurality of sets of schedule times and dates at

which a patient is to take a medication specified by a prescription, periodically

comparing within the carrier the internal values of time and date with the schedule time

and dates, and activating the annunciator element upon the internal values of time and

date matching a set of schedule time and schedule date.

Leigh-Spencer discloses:

alarms including amplifiers, large flashing lights, and/or vibrators for

patients within the portable module (Fig. 6A, col. 7 line 60 to col. 8 line 3);

downloading alarm instructions to the module microprocessor from the

programming station communication interface to the module communication

interface by a pharmacist, wherein alarm instructions provide specific times of

day for taking the medication (Fig. 1 and 6D, col. 1 lines 5-15, col. 2 lines 15-30,

col. 2 lines 40-45, col. 4 lines 18-34, col. 5 lines 29-33, col. 6 lines 29-40, col. 8

lines 7-15, col. 9 line 52 to col. 10 line 23, col. 11 lines 45-50);

providing an alarm timer that provides a "time-of-day" alarm which will

continue until the alarm is acknowledged by the patient in order to provide

specific times of an alarm and to help ensure compliance with the reminder,

wherein the programming station includes a set alarm module for setting the

portable module alarm times and the set alarm module has a number of does

command and time of dose command for determining the portable module alarm

times, wherein the module microprocessor generates an alarm signal

corresponding to the alarm instructions (time the dosage is due) (col. 2 lines 20-

25, col. 3 line 62 to col. 4 line 2, col. 4 lines 33-35, col. 9 lines 31-40, 13 lines 8-

11).

As per the step of comparing internal values of time with schedule times and

dates, it is noted that in order to detect an alarm signal is needed such as that disclosed

in Leigh-Spencer, it would be required by the portable module to provide a comparison

between the alarm instructions (i.e., time of a dosage) with the internal time of the

carrier to detect the alarm times.

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the aforementioned features of Leigh-Spencer within

the method of Gombrich with the motivation of increasing the effectiveness of treatment

and reducing harm to a patient by providing a reminder device to ensure a patient

follows the administration instructions of medication, including the specific time of day

and dose of medication the patient should take (Leigh-Spencer; col. 1 lines 15-25) and

increasing compliance with the reminder device (Leigh-Spencer; col. 2 lines 15-30).

(E) As per claim 5, Gombrich discloses entering a user barcode ID prior to downloading

from memory of the PHPT data via the communications port (Fig. 14, col. 16 lines 3-57,

col. 24 lines 11-36, and col. 37 line 22 to col. 40 line 2).

(F) Claim 7 differs from claim 1 by reciting the following steps "entering a first access

code into said carrier to enable software access" and "entering a second access code

into the carrier to enable software access." As per these steps, Gombrich discloses:

(a) entering an ID and password prior to accessing the PHPT to receive

information at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col.

18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col.

40 line 2); and

(b) entering a user barcode ID prior to downloading from memory of the PHPT

data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and

col. 37 line 22 to col. 40 line 2).

As per the recitation of "said data being in a wholly intangible digital form,"

Gombrich discloses information stored in appropriate data files contained in computer

system memory (col. 22 lines 41-43). It is respectfully submitted that data stored in

computer memory is data in "digital form".

The remainder of claim 7 repeats the same limitations as claim 1, and is

therefore rejected for the same reasons given above, and incorporated herein.

(G) Claims 8-10 and 13 repeat the same limitations as claims 3-4, and are therefore

rejected for the same reasons given for those claims, and incorporated herein.

(H) As per claims 14 and 19, Gombrich discloses a system for providing accurate

identification of a patient and for items relating to a patient such as drugs (col. 1 lines 9-

17 and col. 2 lines 36-45) comprising:

(a) a housing (col. 4 line 63 to col. 5 line 1-2);

(b) a programmed microprocessor (col. 12 lines 14-66);

(c) an LCD display and keypad for displaying information, wherein the keyboard

and LCD are disposed on the surface of the housing and are connected to the

programmed microprocessor (Fig. 26, col. 4 line 63 to col. 5 line 1-2, col. 5 line 35 to

col. 6 line 11, col. 12 lines 14-66);

(d) interface means, including a port for connection to external systems and I/O channels such as terminals and a computer system, for communicating data using RF or infrared signals (Fig. 1, col. 4 line 21 to col. 6 line 11, and col. 12 lines 14-66);

(e) memory associated with a programmed microprocessor within the bar code reading device housing (col. 12 lines 14-66) to:

(1) receive at the PHPT (also called the bar code reading device) prescription information through the interface, wherein prescription information includes a recommended dosage and time to administer drugs (col. 15 line 51 to col. 16 line 17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24); and

(2) download from memory of the PHPT data via the communications port, wherein the data includes drug information, such as drugs administered (col. 24 lines 11-36).

The remaining components of system claim 14 have been fully addressed in the rejection of method claims 1 and 7 above, and therefore the remainder claim 14 is rejected for the same reasons given above, and incorporated herein.

(I) Claims 15-17 repeat the same limitations as claims 3-4, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

(J) As per claim 18, Gombrich discloses:

a keypad on the PHPT such as a HOLD key and SEND key, wherein the keypad

is within the housing of the PHPT for inputting data into the microprocessor of the PHPT

(col. 12 lines 14-66, col. 16 lines 18-57, col. 27 line 16 to col. 30 line 46);

providing an alert if a particular drug administration is overdue and/or improper at

a portable bar code reading device (col. 2 line 67 to col. 3 line 4 and col. 17 lines 37-

59);

storing and displaying upon request six to ten previously recorded and

administered PRN or other controlled drug administered and the times they were

administered in the LCD of the bar code reading device (col. 2 lines 41-45, col. 3 lines

10-18, col. 3 lines 47-53, col. 5 lines 36-48, col. 14 lines 40-64, col. 16 lines 49-55, and

col. 24 lines 11-36) and providing a green status light or other appropriate indication on

the LCD display of the bar code reading device when a drug is administered and

automatically recording the drug was administered, and pushing a button on the bar

code reading device if the treatment did not occur (col. 16 line 67 to col. 17 line 29).

The remainder of claim 18 repeats the same limitations as claim 4, and is

therefore rejected for the same reasons given for claim 4, and incorporated herein. The

motivation for combining Leigh-Spencer within Gombrich is given above in claim 4, and

incorporated herein.

(K) As per claim 20, Gombrich discloses:

(a) entering an ID and password prior to accessing the PHPT to receive

information at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col.

18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col.

40 line 2); and

(b) entering a user barcode ID prior to downloading from memory of the PHPT

data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and

col. 37 line 22 to col. 40 line 2).

(L) As per claim 21, Gombrich discloses:

(a) entering an ID and password prior to accessing the PHPT to receive

information at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col.

18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col.

40 line 2);

(b) entering dosages by use of a key and storing a record of the most recent

dosages (reads on "adding..." and "changing...") (col. 16 lines 18-57)

(c) entering a user barcode ID prior to downloading from memory of the PHPT

data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and

col. 37 line 22 to col. 40 line 2); and

(d) entering and recording the drug prescription as being approved for a

particular patient by a pharmacist (reads on "updating patient information) (Fig. 14, col.

14 line 40 to col. 15 line 48, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to

col. 40 line 2).

The remainder of claim 21 repeats the same limitations as those in claim 1, and

is therefore rejected for the same reasons given for claim 1, and incorporated herein.

2.   Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Goetz (6,397,190) in view of the Computer Science Telecommunication Board (For the

Record Protecting Electronic Health Information, Computer Science Telecommunication

Board National Research Council, National Academy Press, Washington, DC, July

1997).

(A) As per claim 1, Goetz discloses a method for managing prescribed medications

comprising:

        (a) providing an electronic component, such as a handler/ owner component

containing a smart card or a veterinarian component containing a smart card (see Fig.

1) (reads on "digital prescription carrier"), capable of scheduling and tracking a number

of different prescriptions and administration frequencies, wherein the electronic

component includes read/write memory such as the smart card and an infrared

communication interface (Abstract, Fig. 1, col. 2 lines 16-25, col. 4 lines 15-45, col. 5

lines 47-52, col. 6 lines 44-52, col. 9 line 19 to col. 10 line 14, col. 17 lines 20-35, and

col. 18 lines 19-38);

        (b) transferring prescription information by a veterinarian (reads on "prescriber")

into the electronic component through the communication interface, wherein the

prescription information includes medication name and purpose, dosage, frequency,

duration, and any special considerations in consuming the medication (col. 1 line 60 to

col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12

lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);

(c) bringing an electronic component by a handler/owner (reads on "patient") to a

pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

(d) importing prescription information from an electronic component through a

communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

and

(e) filling a prescription at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines

30-48).

Goetz fails to expressly disclose using the method for managing prescribed

medications in a traditional medical environment. It is noted that the Goetz method is

used in a veterinary medical environment. It is respectfully submitted that at the time

the invention was made, the skilled artisan would have found it an obvious modification

to use Goetz's method in a traditional medical environment with the motivation of

ensuring patients are taking medications are correctly, minimizing the number of errors

in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col.

1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

Goetz does not expressly disclose the steps of "encrypting prescription data

defining a prescription so that the data would be indecipherable without appropriate

computer decryption software," "decrypting said prescription data from indecipherable

form into a form that would be decipherable," and "wherein the uploading and

downloading steps are each accomplished by a data transfer that occurs without

physical contact." However, Goetz teaches providing security, via coding features and

data encryption, to prevent unauthorized use and access to data encoded on the smart

card or within the handler/owner component (col. 2 lines 38-47, col. 5 lines 20-25).

The Computer Science Telecommunication Board teaches in a health care

setting in a health care information system, encrypting chunks of information

(components of the patient record, including text, laboratory results, and images) by a

server through software when the information is transmitted over a network such as the

Internet, and then decrypting the chunks of information by special access software to

allow viewing of the information, wherein the software is designed to only allow

accessing and viewing of the information by receipt of properly authenticated user

credentials (reads on "indecipherable without appropriate computer decryption

software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the encryption and decryption techniques disclosed in

Computer Science Telecommunication Board within the method taught by Goetz with

the motivation of controlling the use of information in order to protect the privacy of

patients (Computer Science Telecommunication Board, pg. 12, 120) and preventing

unauthorized use and access to data (Goetz; col. 5 lines 20-25).

As per the recitation of "wherein the uploading and downloading steps are each

accomplished by a data transfer that occurs without physical contact," it is respectfully

submitted that Goetz teaches transferring prescription information by a veterinarian

(reads on "prescriber") into the electronic component through the communication

interface, wherein the prescription information includes medication name and purpose,

dosage, frequency, duration, and any special considerations in consuming the

medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line

3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23

line 4) and importing prescription information from an electronic component through a

communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48).

Goetz discloses the communication interface comprising an infrared communication

link. It is respectfully submitted that infrared is a wireless communication, and therefore

infrared is considered to be a form of "the uploading and downloading steps are each

accomplished by a data transfer that occurs without physical contact."

(B) As per claim 2, Goetz discloses entering a password or personal identification

number (PIN) to access prescription information stored in an electronic component prior

to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and

col. 11 lines 3-24).

(C) As per claim 3, Goetz discloses a method for managing prescribed medications

including:

(a) operating a scheduling and alarm function for prescribed treatments or

medications within an electronic component to generate internal values of date and time

(Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col.

19 lines 5-22);

(b) providing an electronic component with an input button interfaced to an alarm

(Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col.

19 lines 5-22);

(c) pressing an input button to accept or acknowledge administering a

prescription (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15

lines 24-46, col. 19 lines 5-22); and

(d) logging in memory the time/date when the prescribed medication is

administered (Fig. 7, col. 2 lines 5-15, col. 4 lines 15-26, col. 8 lines 23-53, col. 13 lines

40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22).

(D) As per claim 4, Goetz discloses a method for managing prescribed medications

including:

(a) providing an electronic component with an alarm, wherein the alarm is

audible, visual, or tactile such as a vibrator device (col. 5 lines 25-45);

(b) inputting into an electronic component by a pharmacist, prescription

information defining the desired medication, total dosage, and a schedule for

administering each medication including the date and time (col. 11 line 24 to col. 12 line

16 and col. 13 lines 40-67);

(c) comparing the current time and date to the time and date tag for each active

prescription stored in the electronic component (col. 13 lines 40-67); and

(d) generating an alarm when a dose of a prescription has time and date tags

equal to or less than the current time and date (col. 13 lines 40-67).

(E) As per claim 5, Goetz discloses entering a password or personal identification

number (PIN) to access prescription information stored in an electronic component prior

to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and

col. 11 lines 3-24). It is respectfully submitted that it would have been obvious to one

having ordinary skill in the art at the time of the invention to have utilized multiple

passwords and/or PINs (i.e., a second access code) within the system taught

collectively by Goetz and Computer Science Telecommunication Board with the

motivation of improving the security of the system.

(F) As per claim 6, Goetz discloses a method for managing prescribed medications

including:

    (a) uploading prescribed medication data for one or more medications into an

electronic component through a communication interface by a veterinarian or health

care specialist (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10

lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and

col. 22 line 42 to col. 23 line 4);

    (b) downloading prescribed medication data through a communication interface

(col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12

line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4); and

    (c) filling one or more prescriptions defined by prescribed medication data (col. 6

lines 2-14 and col. 10 lines 30-48).

(G) As per claim 7, Goetz discloses a method for managing prescribed medications

comprising:

(a) providing an electronic component, such as a handler/ owner component

containing a smart card or a veterinarian component containing a smart card (see Fig.

1) (reads on "digital prescription carrier"), capable of scheduling and tracking a number

of different prescriptions and administration frequencies, wherein the electronic

component includes read/write memory such as the smart card and an infrared

communication interface (Abstract, Fig. 1, col. 2 lines 16-25, col. 4 lines 15-45, col. 5

lines 47-52, col. 6 lines 44-52, col. 9 line 19 to col. 10 line 14, col. 17 lines 20-35, and

col. 18 lines 19-38);

(b) transferring prescription information into the electronic component through

the communication interface, wherein the prescription information includes medication

name and purpose, dosage, frequency, duration, and any special considerations in

consuming the medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-

14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22

line 42 to col. 23 line 4);

(c) bringing an electronic component by a handler/owner (reads on "patient") to a

pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

(d) importing prescription information from an electronic component through a

communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

and

(e) filling a prescription at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48).

Further, Goetz discloses entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (reads on "first access code") (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24).

Further, Claim 7 includes the recitation of a "second access code" and the "first access code." As per this feature, note the discussion above with respect to Goetz's disclosure of the first access code (see Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24 within Goetz). It is respectfully submitted that it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized multiple passwords and/or PINs within the Goetz system with the motivation of improving the security of the system.

Goetz fails to expressly disclose using the method for managing prescribed medications in a traditional medical environment. It is noted that the Goetz method is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's method in a traditional medical environment with the motivation of ensuring patients are taking medications are correctly, minimizing the number of errors in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

As per the recitation of "said data being in a wholly intangible digital form," Goetz discloses data being transferred via an infrared communication link and stored in a database (col. 17 lines 20-35). It is respectfully submitted that data stored in a computer database is data in "digital form".

Goetz fails to expressly disclose encrypting said prescription data so that said data would be indecipherable without appropriate computer decryption software and decrypting the prescription data to convert the data into an intelligible form.

However, Goetz teaches providing security, via coding features and data encryption, to prevent unauthorized use and access to data encoded on the smart card or within the handler/owner component (col. 2 lines 38-47, col. 5 lines 20-25).

The Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (reads on "indecipherable without appropriate computer decryption software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the method taught by Goetz with

the motivation of controlling the use of information in order to protect the privacy of

patients (Computer Science Telecommunication Board, pg. 12, 120) and preventing

unauthorized use and access to data (Goetz; col. 5 lines 20-25).

(I) Claims 8-9 and 11-13 repeat the same limitations of claims 1-6, and are therefore

rejected for the same reasons given for those claims.

(J) As per claim 10, Goetz discloses an electronic component with an alarm, wherein

the alarm is a vibrator device (col. 5 lines 25-45 and col. 8 lines 23-53).

(K) As per claim 14, Goetz discloses an electronic component for storing prescription

data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col.

21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:

(a) a housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14);

(b) a central processing unit enclosed within the housing (Fig. 8A and 8B, col. 9

line 50 to col. 10 line 14);

(c) an LCD screen included in the housing and interfaced with the CPU, and

capable of displaying alphanumeric characters (Fig. 25-43, col. 5 lines 5-10, and col. 9

line 50 to col. 10 line 14);

(d) electronic circuitry enclosed in the housing and interfaced to the CPU,

wherein the electronic circuitry interfaces the CPU to an external personal computer

(Fig. 25-43, col. 5 lines 5-10, and col. 9 line 19 to col. 10 line 14);

(e) memory enclosed in the housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14); and

(f) prescription software stored in memory to be processed by the CPU (col. 7 lines 25-38 and col. 12 line 31) to enable uploading prescribed medication data for one or more medications into memory through a communication interface by a veterinarian (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10 lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4) and downloading prescribed medication data through a communication interface at a clinic pharmacy (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4).

Goetz fails to expressly disclose using a digital prescription carrier apparatus for managing prescribed medications in a traditional medical environment. It is noted that the Goetz system is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's system in a traditional medical environment with the motivation of ensuring patients are taking medications correctly, minimizing the number of errors in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

Goetz fails to expressly disclose encrypting software for scrambling prescription data that represents a prescription into a form that is unintelligible and unreadable, said

encrypting software further capable of converting encrypted prescription data to a readable form.

Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the system taught by Goetz with the motivation of controlling the use of information in order to protect the privacy of patients (Computer Science Telecommunication Board, pg. 12, 120) and preventing unauthorized use and access to data (Goetz; col. 5 lines 20-25).

(L) Claims 15-16 repeat the same limitations as claims 3-4 and 14, and are therefore rejected for the same reasons given for those claims.

(M) As per claim 17, Goetz discloses an alarm device, wherein the alert device is an

audible alarm interfaced to a CPU or a vibrating device interfaced to a CPU (col. 4 lines

37-67 and col. 5 lines 5-36).

(N) As per claim 18, Goetz discloses an electronic component for storing prescription

data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col.

21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:

         (a) a set of button controls positioned on the housing and interfaced to the CPU

(Fig. 25-43 and col. 9 line 50 to col. 10 line 14);

         (b) prescription software causing transferred prescription data to generate a

schedule of dose times for a medication represented by prescription data (Fig. 8A and

8B and 25-43, col. 9 line 50 to col. 10 line 14, col. 10 lines 30-48, and col. 13 lines 40-

53); and

         (c) operation of button controls enabling a review of scheduled dose times for a

medication, wherein the schedule is displayed on an LCD device (Fig. 8A and 8B and

25-43, col. 9 line 50 to col. 10 line 14, and col. 10 lines 30-48, and col. 13 lines 40-53).

(O) Claim 19 repeats the same limitations as claim 5, and is therefore rejected for the

same reasons given for claim 5.

(P) As per claim 20, Goetz discloses entering a password or personal identification

number (PIN) to access prescription information stored in an electronic component prior

to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and

col. 11 lines 3-24). Further, claim 20 includes the recitation of a "second access code".

As per this feature, note the discussion above with respect to Goetz's disclosure of the

first access code (see Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24 within

Goetz). It is respectfully submitted that it would have been obvious to one having

ordinary skill in the art at the time of the invention to have utilized multiple passwords

and/or PINs within the Goetz and Computer Science Telecommunication Board system

with the motivation of improving the security of the system.

(Q) As per claim 21, Goetz discloses:

     (a) entering a password or personal identification number (PIN) to access

prescription information stored in an electronic component prior to transferring data to

and from the component (reads on "first access code") (Fig. 33 and 35, col. 2 lines 38-

46, and col. 11 lines 3-24);

     (b) adding medication data for a prescription (col. 11 line 24 to col. 12 line 61);

and

     (c) writing and supplying data from a prescription information sheet in addition to

medication administration information (reads on "updating") (col. 6 lines 15-43).

     As per the step of "endowing the pharmacist with a second access code", note

the discussion above with respect to Goetz's disclosure of the first access code. It is

respectfully submitted that it would have been obvious to one having ordinary skill in the

art at the time of the invention to have utilized multiple passwords and/or PINs within the

system taught collectively by Goetz and Computer Science Telecommunication Board

with the motivation of improving the security of the system.

(11)   Response to Argument

In the Appeal Brief filed 26 January 2004, Appellant makes the following

arguments:

I.   The Final Rejection erroneously rejected claims 1-21 as obvious over the

combination of Goetz in view of an article published by the Computer Science

Telecommunications Board because:

A.   The Appellants have submitted respective affidavits swearing that the

subject matter was reduced to practice prior to January of 1997, therefore Goetz is not

prior art.

B.   The Final Rejection erroneously required corroborating evidence to

accompany the affidavit submitted under 37 CFR 1.131.

C.   Assuming arguendo, that affidavits submitted under 37 CFR 1.131 require

corroboration, a requirement for corroboration has clearly been met by the documents

submitted with the affidavits filed in this case.

D.   Even if Goetz qualifies as prior art, the rejection of claims 1-21 as obvious

over Goetz and the article of the Computer Science Telecommunications Board is

improper because Goetz and the article fail to establish prima facie obviousness of the

claimed combination.

II.   The Final Rejection erroneously rejected claims 1-21 under 35 USC 103(a) as

unpatentable over the combined teachings of Gombrich '372, Leigh-Spencer '802, and

a publication of the Computer Science Telecommunications Board, because these

references fail to establish prima facie obviousness.

        A.   The Final Rejection erroneously rejected claims 1-6, 20, and 21 as

obvious over the combined teachings of Gombrich, Leigh-Spencer and an article

published by the Computer Science Telecommunications Board because these

references fail to establish prima facie obviousness of the claimed elements

                1.   Gombrich, Leigh-Spencer, and an article published by the

Computer Science Telecommunications Board fail to show, teach, or suggest each and

every claimed limitation.

                2.   There is no suggestion or motivation to combine the teachings of

the Computer Science Telecommunications Board article with the disclosure of

Gombrich or Leigh-Spencer.

        B.   The Final Rejection erroneously rejected claims 7-13 as obvious over the

combined teachings of Gombrich, Leigh-Spencer, and an article published by the

Computer Science Telecommunications Board because these references fail to

combine to establish prima facie obviousness of the claimed combination.

        C.   The Final Rejection erroneously rejected claims 14-18 as obvious over the

combined teachings of Gombrich, Leigh-Spencer, and an article published by the

Computer Science Telecommunications Board because these references fail to

combine to establish prima facie obviousness of the claimed combination

      1.   The Appellant rewrote claim 14 in accord with the instructions of the

Supervisory Examiner, who agreed that the claim, as submitted, would distinguish over

the art.

      2.   Gombrich, Leigh-Spencer, and an article published by the

Computer Science Telecommunications Board fail to show, teach, or suggest each and

every claimed limitation.

III.   The Examiner erroneously rejected claims 1, 7, and 14 as unpatentable under 35

U.S.C. 132, because the material added by amendment was not new matter.

I.   With respect to the affidavit submitted to overcome the Goetz reference

and with respect to the features of claims 1-21 rejected as obvious in view of

Goetz and the Computer Science Telecommunications Board

(A) In reference to the Appellant's arguments regarding inventorship, the Examiner

respectfully submits that several of the papers filed (see Paper No. 5 and 11) only listed

Thomas Stoll as the inventor. However, in view of Appellant's arguments and the

declaration for this application, the Examiner respectfully submits that both Thomas

Stoll and Karl Schmidt are the correct inventors for this application. Thus, the Examiner

withdraws the arguments related to inventorship.

(B)   In reference to the Appellant's arguments that the Examiner erroneously required

corroborating evidence in the form of documents to accompany the affidavit submitted

under 37 CFR 1.131, it is respectfully submitted that the Examiner <u>never asked</u> for

corroborating evidence of the inventor's statements. The Examiner asked the Appellant

numerous times to clarify the record, specifically the affidavits, to show that the

invention was reduced to practice prior to December 1997. As such, **the Examiner**

requested that Appellant submit FACTS clearly supported by evidence. According

to MPEP § 715.07, the essential thing to be shown under 37 CFR 1.131 is priority of

invention and this may be done by any satisfactory evidence of the fact. FACTS, not

conclusions, must be alleged. Evidence in the form of exhibits may accompany the

Affidavit or declaration. Each exhibit relied upon should be specifically referred to in the

Affidavit or declaration, in terms of what it is relied upon to show. In view of MPEP §

715.07, Appellant did not submit satisfactory evidence of the facts within the statements

of the Affidavit. A general allegation that the invention was completed prior to the date

of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224

(Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her

invention was conceived or reduced to practice prior to the reference date, without a

statement of facts demonstrating the correctness of this conclusion, is insufficient to

satisfy 37 CFR 1.131. 37 CFR 1.131(b) requires that <u>original exhibits of drawings or</u>

<u>records, or photocopies</u> thereof, accompany and form part of the Affidavit or declaration

or their absence satisfactorily explained.

With regards to Appellant's arguments that the Appellant's sworn testimony

confirms that each and every claimed element was in possession of the Appellants, and

in fact reduced to practice prior to the effective filing date of Goetz, the Examiner

respectfully disagrees. For example, Appellant provides no clear nexus between the

Affidavit statements that Karl P. Schmidt contributed to the reduction to practice of the

method step, providing an infrared data communication interface, claimed in this

application no later than December 1997 and the claimed subject matter as the

Appellant does not point to evidence of this feature within Annexes A-F (see Paper No.

14 for Affidavit of Karl Schmidt and Paper No. 16 for Annexes). Thus, the Affidavit of

Karl P. Schmidt was deemed insufficient according to the requirements of MPEP §

715.07 by the Examiner.

Further, Appellant argues that the affidavit of Mr. Stoll further establishes that, in

the event there are differences between the subject matter set forth in the claims and

the subject matter set forth in the affidavit, then these differences – if any are found –

are merely obvious variations of the claimed invention, and would have been obvious to

one having ordinary skill in the applicable art. In response, the Examiner clearly pointed

out in previous Office Actions (see paper number 12, page 23, section B and paper

number 17, pages 36-37, section C) that according to MPEP § 715.02, the Appellant

must show **why the differences** between the claimed invention and the showing under

37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of

Appellant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the

activity. However, Appellant has provided no explanation of the differences between

the claimed invention and the showing under 37 CFR 1.131, in view of Appellant's 37

CFR 1.131 evidence, and why these differences would have been obvious. Appellant

instead provided blanket statements addressing the obviousness issue. Note,

Appellant's statements in the Affidavit (paper number 15) at page 3 section 4, "any

differences between the method steps set forth in paragraph 3 and the method steps

claimed in the pending application would have been obvious to one having ordinary skill

in the art" and states in the Affidavit (paper number 15) at page 5 section 6, "any

differences between the aspects of my digital prescription carrier invention that are set

forth in paragraph 4 above and the aspects that are set forth in the pending application

would have been obvious to one having ordinary skill in the art." **It was requested in**

response to the previous Office Actions (paper number 12 and 17) that Appellant

clarify this issue and clearly explain why the differences between the claimed

invention and the showing under 37 CFR 1.131 would have been obvious to one

of ordinary skill in the art, in view of Appellant's 37 CFR 1.131 evidence, prior to

the effective date of the reference(s) or the activity. However, Appellant failed to

do so and has only provided blanket statements claiming obviousness.

In response to Appellant's arguments that Mr. Stoll enumerated the facts in the

Affidavit (paper number 15) by reciting twenty-one individually-enumerated facts at

paragraph 2 and eighteen individually enumerated facts at paragraph 5, the Examiner

respectfully submits that the issue is the lack of evidence that the Appellant's reduced to

practice the claimed invention in December 1997, not enumerated facts. For example,

at pages 1-4, paragraphs 3 and 5, of the Affidavit (paper number 15), the Appellant

states that he reduced to practice the following elements and method steps in combination:

(a) entering a prescription into said carrier by a physician through an encryption system comprising both a hardware and software component contained within said carrier;

(b) providing within said carrier an encryption system such that said prescription information cannot be entered or altered by anyone other than a pharmacist or a physician who has access to the encryption key software;

(c) uploading encrypted information for a drug prescription into said carrier through said interface, said prescription calling for use of a selected medication at a selected dosage on a selected schedule;

(d) de-scrambling or decrypting the encrypted data so that the prescription data could be read by a pharmacist;

(e) entering data acknowledging that the prescription has been filled;

(f) encryption and decryption software capable of converting digital prescription data to an indecipherable, unreadable form, and further capable of returning encrypted data to a digital form that is readable and decipherable; and

(g) an interface for allowing the transfer of prescription data across the interface without requiring physical or electrical contact.

Appellant did not point out the portions of the submitted printouts (Annexes A-F of paper number 16) tied to the aforementioned steps and elements recited in (a)-(g) and as per the language of claims 1, 7, and 14. Appellant was respectfully requested to

point out the portions of the Annexes that are related to these limitations in claims 1, 7,

and 14 and described in sections (a)-(g) above, and failed to do so. As such, because

these limitations were not shown in the Annexes and for reasons to be discussed below,

the Examiner deemed the Affidavit of Thomas Stoll insufficient according to the

requirements of MPEP § 715.07.

In summary, the Examiner respectfully submits that the Affidavit of Thomas Stoll

(paper numbers 11 and 15) was previously submitted by the Appellant in two separate

responses. The Examiner has provided detailed explanations of why the Affidavits are

ineffective to overcome the Goetz reference (see paper numbers 7, 12, and 17). The

Appellant has still failed to address the deficiencies of the Affidavit of Thomas Stoll by

providing FACTS clearly tied to evidence that that the Appellant had indeed reduced to

practice the claimed invention in December 1997. Instead of providing facts to the

Examiner, the Appellant appears to be relying solely on *Ex parte Hook and Cook* as a

reason for not providing evidence that the claimed invention was reduced to practice in

December of 1997. Further, Appellant appears to argue that all the Appellant is

required to do in an affidavit is say the Appellant had the invention. As discussed

above, Appellant is required under 37 CFR 1.131(B) to provide original exhibits of

drawings or records, or photocopies thereof, as part of the affidavit for the purpose of

evidence that the claimed invention actually was reduced to practice prior to December

1997, and the Examiner respectfully submits that the Appellant has failed to provide

satisfactory evidence of the facts.

(C) In reference to Appellant's arguments that assuming arguendo, that affidavits

submitted under 37 CFR 1.131 require corroboration, a requirement for corroboration

has clearly been met by the documents submitted with the affidavits filed in this case,

the Examiner respectfully submits that the documents, namely the Affidavit of Thomas

Stoll (paper no. 15) and correspondence (paper no. 16), including the Medx System

flowchart (Annex A), and the Kemnitzer Design correspondence dated 27 December

1997 (Annex B), submitted are insufficient because the Affidavit and correspondence

are not commensurate in scope with the claimed invention, and further the Affidavit fails

to show why the differences between the claimed invention and the showing under 37

 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of

Appellant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the

activity (see MPEP § 715.02).

In particular, it is respectfully submitted that the features recited on page 5 of the

Affidavit are not directly tied to the flowchart given in Annex A. At least the following

features are not found in Annex A, however in the Affidavit, Appellant states he had

possession of the claimed features:

i.   providing a digital prescription carrier including a read/write memory and a

communication interface;

ii.   entering a first access code into said carrier to enable software access

thereto;

      iii.   uploading prescription data defining a prescription into said carrier through

said interface, said prescription calling for the use of a selected medication of a selected

dosage on a selected schedule.

      Appellant's reliance on Annex A to establish reduction to practice and to antedate

the applied reference is non-persuasive as the correlation between the flowchart in

Annex A and the features explicitly recited in the instant claims are not clearly

established (i.e., no establishment of the elements of the flow chart that correspond with

the claims), and the Appellant fails to address why certain features are obvious when

certain claimed features are not shown in Annex A.

      Secondly, the evidence provided in statements in the Affidavit on pages 6-8 does

not appear to have the proper support within Annex B. Appellant states that the feature

of "uploading, by a prescriber, of prescription data representing a prescription into

memory circuitry" is supported by Annex B stating "... the device retains history of

response that can be downloaded by the pharmacist (par. 1 lines 10-11)." However, it

is noted that uploading data to memory is not equivalent to downloading data from a

device, and therefore fails to explicitly show the feature of uploading.

      Further, Appellant states that the features of "prescription software causing

uploaded prescription data to generate a schedule of dose times for a medication

represented by prescription data," and "a real-time clock/calendar positioned within the

housing and interfaced to the CPU," is supported by Annex B stating "This is a product

that would aid users in prescription compliance... that would 'remind' the user of a

prescription to be taken (par. 1 lines 2-4)." However, it is noted that Annex B fails to

recite the features of prescription software causing uploaded prescription data to

generate a schedule of dose times, nor does it recite anywhere a real-time

clock/calendar positioned within the housing.

Also, Appellant states that the feature of an "input/output (I/O) interface circuitry

positioned in said housing and interfaced to said CPU, said I/O circuitry being capable

of interfacing said CPU to an external computer to exchange data therewith" is

supported by Annex B stating "The device retains a history of response that can be

downloaded by the pharmacist, who can program this device through a PC" (Par. 1,

lines 10-11). It is noted that Annex B fails to recite the features of input/output circuitry

or the feature of interfacing with a CPU to an external computer to exchange data.

It is respectfully submitted that Appellant's reliance on Annex B to establish

reduction to practice and to antedate the applied reference is non-persuasive as the

correlation between the Affidavit and correspondence in Annex B and the features

explicitly recited in the instant claims are not clearly established, and the Appellant fails

to address why certain features are obvious when certain claimed features are not

shown in Annex B (such as access codes recited in the claimed invention and the

features discussed above).

It is noted that both Annex E and Annex F fail to establish a correlation between

the correspondence and the claimed subject matter. The Appellant has not pointed out

the specific portions of the submitted materials tied to the claimed subject matter.

Furthermore, both Annex E and Annex F are dated after December 1997.

In addition to the issues raised above regarding the Affidavit of Thomas Stoll and Annexes A-F, firstly, at page 1, paragraph 1, of the Affidavit, the Appellant states that the subject matter set forth in claims 1-19 was <u>invented</u> no later than December 1997. Further, at pages 1-3, paragraph 3, of the Affidavit, the Appellant states that the elements and methods of claims 1-19 were <u>reduced to practice</u> no later than December 1997.

According to MPEP § 715.04, in general, <u>proof of actual reduction to practice</u> requires a showing that the apparatus actually existed and worked for its intended purpose. The Affidavit includes correspondence from the Appellant to Kemnitzer Design, Inc. dated 27 December 1997 (Annex B) and correspondence from the Appellant to the Appellant's patent agent dated 1 October 1998 (Annex F) which Appellant states were sent after the invention was reduced to practice (see page 6(b) and 8(f) of Affidavit). However, it is entirely unclear to the Examiner how the invention could have been reduced to practice no later than December 1997 for the following reasons:

(a) The Kemnitzer document (Annex B) states in paragraph 1, "... a product that <u>will</u> aid users in prescription compliance. As <u>conceived</u> by Medical Innovations, Inc., the product <u>would be</u> the size of a pager. It <u>would</u> have a battery powered, two line LED display that <u>would</u> 'remind' the user of a prescription to be taken... (emphasis added)" Further, at paragraph 4, the document states "Medical Innovations, Inc. wishes to solicit input from potential users and prescribers <u>prior to committing to a formal design/build</u>

program. Accordingly it has asked Kemnitzer Design, Inc. to prepare a proposal for

production of a non-functional visual model (emphasis added)."

It is respectfully submitted that it is unclear how the invention was reduced to

practice no later than December 1997, when according to the Kemnitzer document

dated December 27, 1997, the Appellant had not committed to a formal design and was

still in the process of building a non-functional, visual model. As stated above, proof of

actual reduction to practice requires a showing that the apparatus actually existed and

worked for its intended purpose. Annex B fails to show that the apparatus actually

existed and worked for its intended purpose. It appears, according to Annex B, the

invention had been conceived on paper and the Appellant appears to have determined

what the functions of the product would be in the future. However, it is not clear from

Annex B that the claimed invention was reduced to practice no later than December

1997.

(b) The correspondence from the Appellant to the Appellant's patent agent dated

1 October 1998 (Annex F) states in paragraph 1, "Enclosed is a block diagram, a rough

sketch, and a design outline for the MedX product. These items were prepared by Karl

Schmidt, an electrical engineer helping with the product's design. The product's final

appearance will be different from the sketch, but the sketch may help you conceptualize

the product. After the electronic design is complete an industrial designer will help

create the product's overall appearance..." Further, in the Product Design Outline of

Annex F, there are features with question marks next to them (i.e., appears there are

still questions in the product design) (see page 4 lines 14-17 as an example.)

It is respectfully submitted that it is unclear how the invention was reduced to practice no later than December 1997, when according to the correspondence in Annex F dated 1 October 1998, the Appellant was still completing the product's electronic design. As stated above, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. Annex F fails to show that the apparatus actually existed and worked for its intended purpose. It appears, according to Annex F, the invention had been conceived on paper and the Appellant appears to have determined what the functions of the product *would be* in the future based on the Product Design Outline. However, it is not clear from Annex F that the claimed invention was reduced to practice no later than December 1997.

(c) In the Affidavit at page 6, Appellant states that the correspondence from Karl Schmidt to Thomas Stoll dated 25 September 1998 (Annex E) indicated that the engineer/draftsman had completed drawings of the invention.

It is respectfully submitted that it is unclear how the invention was reduced to practice no later than December 1997, when according to the correspondence in Annex E dated 25 September 1998, the Appellant had completed drawings of the invention. As stated above, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. Annex E fails to show that the apparatus actually existed and worked for its intended purpose. It appears, according to Annex E, the Appellant had determined some components of the product. However, it is not clear from Annex E that the claimed invention was reduced to practice no later than December 1997.

It is noted that according to MPEP § 715.04, "there are some devices so simple

that a mere construction of them is all that is necessary to constitute reduction to

practice." *In re Asahi /America Inc.*, 94-1249 (Fed. Cir. 1995) (Citing *Newkirk v.*

Lulegian, 825 F.2d 1581, 3USPQ2d 1793 (Fed. Cir. 1987) and *Sachs v. Wadsworth*, 48

F.2d 928, 929, 9 USPQ 252, 253 (CCPA 1931). (The claimed restraint coupling held

to be so simple a device that mere construction of it was sufficient to constitute

reduction to practice. Photographs, coupled with articles and a technical report

describing the coupling in detail were sufficient to show reduction to practice.)

However, it is noted that Appellant has not provided photographs, coupled with articles

and a technical report describing the claimed invention in order to establish reduction to

practice no later than December 1997.

Secondly, at pages 1-4, paragraphs 3 and 5, of the Affidavit, the Appellant states

that he reduced to practice the following elements and method steps in combination:

(a) entering a prescription into said carrier by a physician through an encryption

system comprising both a hardware and software component contained within said

carrier;

(b) providing within said carrier an encryption system such that said prescription

information cannot be entered or altered by anyone other than a pharmacist or a

physician who has access to the encryption key software;

(c) uploading encrypted information for a drug prescription into said carrier

through said interface, said prescription calling for use of a selected medication at a

selected dosage on a selected schedule;

(d) de-scrambling or decrypting the encrypted data so that the prescription data

could be read by a pharmacist;

(e) entering data acknowledging that the prescription has been filled;

(f) encryption and decryption software capable of converting digital prescription

data to an indecipherable, unreadable form, and further capable of returning

encrypted data to a digital form that is readable and decipherable; and

(g) an interface for allowing the transfer of prescription data across the interface

without requiring physical or electrical contact.

Appellant has not pointed out the portions of the submitted printouts (Annexes A-F) tied

to the aforementioned steps and elements recited in (a)-(g) and as per the language of

claims 1, 7, and 14. Appellant was respectfully requested to point out the portions of

the Annexes that were related to the limitations in claims 1, 7, and 14 and described in

sections (a)-(g) above, and has failed to point out the portions of the Annexes that were

related to the limitations in claims 1, 7, and 14.

Thirdly, the Affidavit includes a copy of a printout from the corporations database

of the Missouri Secretary of State, verifying an incorporation dated 9 May 1997 (Annex

C) and a copy of an IRS Form 2553 dated 14 March 1998 (Annex D). It is respectfully

submitted there is no clear nexus between the materials and the claimed subject matter.

In particular, Appellant has not pointed out specific portions of the submitted printouts

directly tied to the specific elements or features that are being claimed. For example,

Appellant has not pointed out the portions of the submitted printouts tied to the step of

"uploading prescription data..." as per the language of claims 1, 7, and 14 and the steps

of "entering a first access code" and "entering a second access code" as per the

language of claims 2, 7, and 20. Furthermore, although the printouts are acknowledged

and entered into the record by the Examiner, it is noted there is nothing related to the

language recited in the instant claims within the submitted printouts, and therefore the

printouts appear to be irrelevant to the issues at hand.

Lastly, in response to Appellant's arguments that the Examiner erroneously

misplaced the burden of proof with regard to a potential public disclosure of the

invention, it is noted the Examiner was raising an issue with the Affidavits that required

clarification by the Appellant. The Affidavit and correspondence from Kemnitzer Design

dated 27 December 1997 (Annex B) states that the invention was privately disclosed to

Kemnitzer Design. However, it is respectfully submitted that Annex B fails to contain a

confidentiality agreement, and further states that "Medical Innovations, Inc. wishes to

solicit input from potential users and prescribers prior to committing to a formal

design/build program (par. 3)." According to Garret Corp. v. United States, 422 F.2d

874, 878, 164 USPQ 521, 524 (Ct. Cl.1970), a document is clearly a printed publication

when it is distributed to commercial companies without restriction on use, while

distribution to government agencies and personnel alone may not constitute publication.

Further, according to Annex B, potential users and prescribers provided input prior to a

formal design/build program, and the Affidavit failed to include information on whether

those potential users and prescribers signed confidentiality agreements. Therefore,

Appellant did not provide documentation within the Affidavit stating that both Kemnitzer

Design and potential users and prescribers were under confidentiality agreements, and

it appeared to the Examiner that Annex B may have been disclosed to the public.

Thus, based on the above discussions of the Affidavit, Appellant's reliance on the

Affidavit filed 10 June 2003, including Annex A – Annex F, to show actual reduction to

practice is non-persuasive for the reasons given above in sections A-F. Therefore,

constructive reduction to practice is the filing date of the application, 21 January 2000,

and reduction to practice has not been shown to be earlier than 21 January 2000. It is

noted that December 1997 appears to be when the invention was conceived based on

the documents submitted, and if conception occurred in December 1997, then the

Appellant would need to show due diligence from December 1997 to the date of filing,

21 January 2000. In response to Appellant's arguments at pages 10-11 of the Brief that

the affidavit clearly establishes reduction to practice rather than conception based on

the preambles within the Affidavit, the Examiner respectfully submits that a thorough

discussion of why the Affidavit is insufficient to establish reduction to practice in

December 1997 has been provided above. In addition, the Examiner was simply

pointing out that the evidence provided by the Appellant appeared to be directed

towards establishing conception. However, the Examiner realizes the Appellant was

attempting to establish reduction to practice in December 1997.

Furthermore, it is noted that the last correspondence submitted in the Affidavit

occurred 1 October 1998 (Annex F). However, the present application was not filed

until 21 January 2000. **It is respectfully submitted that an explanation as to what**

occurred during the time period between 1 October 1998 and 21 January 2000 has

not been included within the Affidavit.

(D) In reference to Appellant's arguments that the rejections of claims 1-21 as obvious

over Goetz and the article of the Computer Science Telecommunications Board are

improper because Goetz and the article fail to establish prima facie obviousness of the

claimed combination, the Examiner respectfully notes that the cited references were

never applied as a reference under 35 U.S.C. 102 against the pending claims. As such,

the Examiner respectfully submits that the issue at hand is not whether the applied prior

art specifically teaches the claimed features, *per se*, but rather, whether or not the prior

art, when taken in combination with the knowledge of average skill in the art, would put

the artisan in possession of these features. Regarding this issue, it is well established

that references are evaluated by what they suggest to one versed in the art, rather than

by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of

obviousness is not determined by what the references expressly state but by what they

would reasonably suggest to one of ordinary skill in the art, as supported by decisions in

In re DeLisle 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ

871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988)

(citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further,

it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

      (i)   obviousness does not require absolute predictability;

      (ii)   non-preferred embodiments of prior art must also be considered; and

(iii)   the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references.   In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In the instant case, specifically claims 1, 7, and 14, Goetz discloses <u>an electronic component</u> capable of scheduling and tracking a number of different prescriptions and administration frequencies, wherein the electronic component includes read/write memory and a communication interface, wherein prescription information is transferred into the electronic component through the communication interface, and prescription information is imported from an electronic component through a communication interface at a clinic pharmacy, as clearly set forth in the rejections above (see sections 2A, G, and K.) Goetz clearly discloses a carrier capable of providing the functionality set forth in claims 1, 7, and 14.

As such, it is respectfully submitted that Appellant appears to view the applied

references in a vacuum <u>without considering the knowledge of average skill in the art</u>.

Furthermore, the Examiner submits that the Goetz reference does not teach

away from the applied reference or the Appellant's invention. Goetz suggests several

advantages that the invention is intended to provide for users, including ensuring

patients are taking medications are correctly, minimizing the number of errors in taking

medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines

25-57 and col. 1 line 60 to col. 2 line 25).

In response to Appellant's arguments regarding the combination of the Goetz

and article of the Computer Science Telecommunications Board, the Examiner

respectfully submits that the Appellant is attacking the references individually.

However, one cannot show nonobviousness by attacking references individually where

the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed.

Cir. 1986).

In addition, the test for obviousness is not whether the features of a secondary

reference may be bodily incorporated into the structure of the primary reference; nor is it

that the claimed invention must be expressly suggested in any one or all of the

references. Rather, the test is what the combined teachings of the references would

have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981).

In this case, Goetz discloses <u>an electronic component</u> capable of scheduling and

tracking a number of different prescriptions and administration frequencies, wherein the

electronic component includes read/write memory and a communication interface,

wherein prescription information is transferred into the electronic component through the

communication interface, and prescription information is imported from an electronic

component through a communication interface at a clinic pharmacy, as clearly set forth

in the rejections above (see sections 2A, G, and K) and the article of the Computer

Science Telecommunications Board discloses in a health care setting in a health care

information system, encrypting chunks of information (components of the patient record,

including text, laboratory results, and images) by a server through software when the

information is transmitted over a network such as the Internet, and then decrypting the

chunks of information by special access software to allow viewing of the information,

wherein the software is designed to only allow accessing and viewing of the information

by receipt of properly authenticated user credentials. It is the position of the Examiner

that the skilled artisan would be in possession of a digital prescription carrier using

encryption and decryption, such as that claimed in claims 1, 7, and 14, when

considering the teachings of Goetz and the article of the Computer Science

Telecommunications Board, collectively, in combination with the knowledge of average

skill in the art, for at least the reason that the skilled artisan would readily recognize that

controlling the use of medical information protects the privacy of patients and prevents

unauthorized use and access to data.

As such, it is respectfully submitted that Appellant appears to view each of the applied references separately, in a vacuum, without considering the knowledge of average skill in the art, and that such piecemeal analysis is improper.

II.   With respect to the features of claims 1-21 rejected as unpatentable over the combined teachings of Gombrich '372, Leigh-Spencer '802, and a publication of the Computer Science Telecommunications Board, because these references fail to establish prima facie obviousness

(A) With respect to Appellant's argument that the Examiner fails to establish a prima facie case of obviousness because the combination of references fails to teach or suggest each and every claimed limitation, the Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that she has at least satisfied the burden of presenting a *prima facie* case of obviousness, since she has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Appellant's claimed invention (see section 10 (B) 1 above). Note, for example, the motivation

explicitly stated above in the rejection of claim 1 (i.e., "...motivation of providing an

efficient and cost-effective distribution of portable modules for use by patients and

pharmacists (Leigh-Spencer; col. 2 lines 40-50) and ensuring patient's receive quality

care by ensuring patient receive the proper prescription drugs at the proper time

(Gombrich; col. 1 lines 47-60)") which is based on the teachings of the applied prior art.

(B) In reference to Appellant's arguments that the features of claim 1, namely,

uploading prescription data defining a prescription into said carrier through said

interface, and downloading said prescription data through said interface at said

pharmacy, are not taught by the applied references, the Examiner respectfully submits

that all of the limitations which Appellant disputes as missing in the applied references

have been fully addressed by the Examiner as either being fully disclosed or obvious in

view of the collective teachings of Gombrich, Leigh-Spencer, and/or the Computer

Science Telecommunication Board based on the logic and sound scientific reasoning of

one ordinarily skilled in the art at the time of the invention, as detailed in the remarks

and explanations given in the preceding sections above and in the prior Office Actions

(paper numbers 4, 12, and 17), and incorporated herein. One cannot show

nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA

1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether

the features of a secondary reference may be bodily incorporated into the structure of

the primary reference; nor is it that the claimed invention must be expressly suggested

in any one or all of the references. Rather, the test is what the combined teachings of

the references would have suggested to those of ordinary skill in the art. See *In re*

Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Furthermore, the Examiner respectfully notes that neither of the Gombrich,

Leigh-Spencer, and/or the Computer Science Telecommunication Board references

were ever applied as references under 35 U.S.C. 102 against the pending claims. As

such, the Examiner respectfully submits that the issue at hand is not whether the

applied prior art specifically teaches the claimed features, *per se*, but rather, whether or

not the prior art, <u>when taken in combination with the knowledge of average skill in the</u>

<u>art</u>, would put the artisan in possession of these features. Regarding this issue, it is well

established that references are evaluated by what they suggest to one versed in the art,

rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The

issue of obviousness is not determined by what the references expressly state but by

what they would reasonably suggest to one of ordinary skill in the art, as supported by

decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies*

208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir.

1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)).

Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i)   obviousness does not require absolute predictability;

(ii)   non-preferred embodiments of prior art must also be considered; and

(iii)   the question is not express teaching of references, but what they would

suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is

presumed to know something more about the art than only what is disclosed in the

applied references.   In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies

to some extent on knowledge of persons skilled in the art to complement that which is

disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory

limitation as to the number of references that may be used to demonstrate

obviousness...not what references expressly state but what they would reasonably

suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA),

obviousness is not based on express suggestion, but what references taken collectively

would suggest.

In this case, each limitation recited in claims 1, 2-6, 20, and 21 has been

addressed by the Examiner as either being fully disclosed or obvious in view of the

collective teachings of Gombrich, Leigh-Spencer, and/or the Computer Science

Telecommunication Board based on the logic and sound scientific reasoning of one

ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks

and explanations given above, and incorporated herein.

As such, it is respectfully submitted that Appellant appears to view the applied

references in a vacuum <u>without considering the knowledge of average skill in the art</u>.

In reference to Appellant's specific arguments that Gombrich and Leigh-Spencer

fail to disclose uploading prescription data defining a prescription into said carrier

through said interface and downloading said prescription data through said interface at

said pharmacy, it appears that Appellant's statements are misdescriptive of the full

teachings of the combination of Gombrich and Leigh-Spencer. Gombrich discloses

providing a portable handheld patient terminal (PHPT) with a bar code reader to provide

the main data collection component of patient identification information, wherein the

PHPT allows storage of data relating to patients in memory (reads on "write"), wherein

the PHPT utilizes infrared (IR) transmission/reception by an infrared transmitter/receiver

arrangement or interface to transmit or send data stored in memory (reads on "read)

(col. 3 line 59 to col. 4 line 20, col. 5 line 18 to col. 6 line 11, col. 10 line 57 to col. 11

line 5, col. 12 lines 14-66, col. 23 line 11-36), receiving at the PHPT (also called the bar

code reading device) prescription information through the interface, wherein prescription

information includes a recommended dosage and time to administer drugs entered by a

staff member, secretary, or nurse (reads on "by a prescriber") (col. 15 line 51 to col. 16

line 17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35

line 24), downloading from memory of the PHPT data via the communications port,

wherein the data includes drug information, such as drugs administered (col. 24 lines

11-36). Further, Gombrich includes the input and output of data using infrared

communication or RF communication (col. 10 line 57 to col. 11 line 51, col. 24 lines 11-

36), wherein the RF signals allow for real time data transmission using an RF

transceiver and antenna arrangement. The input and output of data using infrared or

RF signals or infrared are wireless as evidenced by Gombrich (col. 23 15-20), and thus

these wireless communication protocols are considered to be a form of "the uploading

and downloading steps are each accomplished by a data transfer that occurs without

physical contact."

It is respectfully submitted that Gombrich taken collectively with Leigh Spencer

and the Computer Science Telecommunication Board teach the features of claim 1, and

therefore the rejection is maintained.

(B) In response to Appellant's arguments regarding the combination of the Gombrich,

Leigh-Spencer, and the article of the Computer Science Telecommunications Board

with regards to claim 7, the Examiner respectfully submits that the Appellant is attacking

the references individually. However, one cannot show nonobviousness by attacking

references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, the test for obviousness is not whether the features of a secondary

reference may be bodily incorporated into the structure of the primary reference; nor is it

that the claimed invention must be expressly suggested in any one or all of the

references. Rather, the test is what the combined teachings of the references would

have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981).

In this case, Gombrich teaches providing a portable handheld patient terminal

(PHPT) with a bar code reader to provide the main data collection component of patient

identification information, wherein the PHPT utilizes infrared (IR) transmission/reception

by an infrared transmitter/receiver arrangement or interface to transmit or send data

stored in memory, receiving at the PHPT (also called the bar code reading device)

prescription information through the interface, wherein prescription information includes

a recommended dosage and time to administer drugs entered by a staff member,

secretary, or nurse, downloading from memory of the PHPT data via the

communications port, wherein the data includes drug information, such as drugs

administered. Further, Gombrich includes the input and output of data using infrared

communication or RF communication, wherein the RF signals allow for real time data

transmission using an RF transceiver and antenna arrangement. The article of the

Computer Science Telecommunications Board discloses in a health care setting in a

health care information system, encrypting chunks of information (components of the

patient record, including text, laboratory results, and images) by a server through

software when the information is transmitted over a network such as the Internet, and

then decrypting the chunks of information by special access software to allow viewing of

the information, wherein the software is designed to only allow accessing and viewing of

the information by receipt of properly authenticated user credentials. It is the position of

the Examiner that the skilled artisan would be in possession of a digital prescription

carrier using encryption and decryption, such as that claimed in claim 7, when

considering the teachings of Gombrich, Leigh-Spencer, and the article of the Computer

Science Telecommunications Board, collectively, in combination with the knowledge of average skill in the art, for at least the reason that the skilled artisan would readily recognize that controlling the use of medical information protects the privacy of patients and prevents unauthorized use and access to data.

As such, it is respectfully submitted that Appellant appears to view each of the applied references separately, in a vacuum, without considering the knowledge of average skill in the art, and that such piecemeal analysis is improper.

(C) With respect to Appellant's arguments that the combination of Gombrich, Leigh-Spencer, and the article of the Computer Science Telecommunications Board do not collectively teach the steps of claim 21, the Examiner respectfully notes that neither of the Gombrich, Leigh-Spencer, and the article of the Computer Science Telecommunications Board references were ever applied as references under 35 U.S.C. 102 against the pending claims. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, <u>when taken in combination with the knowledge of average skill in the art</u>, would put the artisan in possession of these features. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160

USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071,

1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223

USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*,

192 USPQ 278 (CCPA) that:

(i)   obviousness does not require absolute predictability;

(ii)   non-preferred embodiments of prior art must also be considered; and

(iii)   the question is not express teaching of references, but what they would

suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is

presumed to know something more about the art than only what is disclosed in the

applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies

to some extent on knowledge of persons skilled in the art to complement that which is

disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory

limitation as to the number of references that may be used to demonstrate

obviousness...not what references expressly state but what they would reasonably

suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA),

obviousness is not based on express suggestion, but what references taken collectively

would suggest.

In this case, each limitation recited in claim 21 has been addressed by the

Examiner as either being fully disclosed or obvious in view of the collective teachings of

Gombrich, Leigh-Spencer, and the article of the Computer Science Telecommunications

Board based on the logic and sound scientific reasoning of one ordinarily skilled in the

art at the time of the invention, as clearly detailed in the remarks and explanations given

above, and incorporated herein. In particular, note the teachings of Gombrich

regarding:

entering an ID and password prior to accessing the PHPT to receive information

at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col. 18 line 2,

col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col. 40 line 2);

entering dosages by use of a key and storing a record of the most recent

dosages (reads on "adding..." and "changing...") (col. 16 lines 18-57)

entering a user barcode ID prior to downloading from memory of the PHPT data

via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37

line 22 to col. 40 line 2); and

entering and recording the drug prescription as being approved for a particular

patient by a pharmacist (reads on "updating patient information) (Fig. 14, col. 14 line 40

to col. 15 line 48, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to col. 40 line

2).

As such, it is respectfully submitted that Appellant appears to view the applied

references in a vacuum without considering the knowledge of average skill in the art.

(D) With respect to Appellant's arguments that the applied references, namely

Gombrich, Leigh-Spencer, and the article by the Computer Science

Telecommunications Board do not teach the uploading and downloading steps of claim

7, the Examiner respectfully submits that the Appellant's statements appear to be

misdescriptive of the full teachings of the Gombrich reference.

Gombrich discloses the following:

providing a portable handheld patient terminal (PHPT) with a bar code reader to

provide the main data collection component of patient identification information, wherein

the PHPT allows storage of data relating to patients in memory (reads on "write"),

wherein the PHPT utilizes infrared (IR) transmission/reception by an infrared

transmitter/receiver arrangement or interface to transmit or send data stored in memory

(reads on "read) (col. 3 line 59 to col. 4 line 20, col. 5 line 18 to col. 6 line 11, col. 10 line

57 to col. 11 line 5, col. 12 lines 14-66, col. 23 line 11-36), receiving at the PHPT (also

called the bar code reading device) prescription information through the interface,

wherein prescription information includes a recommended dosage and time to

administer drugs entered by a staff member, secretary, or nurse (reads on "by a

prescriber") (col. 15 line 51 to col. 16 line 17, col. 17 line 37 to col. 18 line 2, col. 26

lines 59-68, and col. 34 line 56 to col. 35 line 24), downloading from memory of the

PHPT data via the communications port, wherein the data includes drug information,

such as drugs administered (col. 24 lines 11-36). Further, Gombrich includes the input

and output of data using infrared communication or RF communication (col. 10 line 57

to col. 11 line 51, col. 24 lines 11-36), wherein the RF signals allow for real time data

transmission using an RF transceiver and antenna arrangement. Further, as per the

recitation of "said data being in a wholly intangible digital form," Gombrich discloses

information stored in appropriate data files contained in computer system memory (col.

22 lines 41-43). It is respectfully submitted that data stored in computer memory is data

in "digital form".

Thus, it is the position of the Examiner that Gombrich taken collectively with

Leigh-Spencer and the article by the Computer Science Telecommunications Board

discloses the features of claim 7.

Appellant's arguments regarding the combination of the article by the Computer

Science Telecommunications Board with Gombrich being improper at page 23 of the

Brief has been addressed above in section C, and is incorporated herein.

(E) With respect to Appellant's arguments that if the Appellant rewrote claim 14, it

would overcome the prior art, it is respectfully submitted that the Examiners never

agreed that the amendments would overcome the prior art. The Examiners only agreed

that the rejections would be reconsidered in light of any newly submitted amendments

and/or arguments (see paper number 13).

(F) With respect to Appellant's arguments that that Gombrich, Leigh-Spencer, and the

article by the Computer Science Telecommunications Board do not teach or suggest

every limitation of claim 14, the Examiner respectfully disagrees.

Firstly, the Examiner respectfully notes that neither of the Gombrich, Leigh-

Spencer, and the article by the Computer Science Telecommunications Board

references were ever applied as references under 35 U.S.C. 102 against the pending

claims. As such, the Examiner respectfully submits that the issue at hand is not

whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, <u>when taken in combination with the knowledge of average skill in the art</u>, would put the artisan in possession of these features. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i)   obviousness does not require absolute predictability;

(ii)   non-preferred embodiments of prior art must also be considered; and

(iii)   the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory

limitation as to the number of references that may be used to demonstrate

obviousness...not what references expressly state but what they would reasonably

suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA),

obviousness is not based on express suggestion, but what references taken collectively

would suggest.

In this case, each limitation recited in claim 14 has been addressed by the

Examiner as either being fully disclosed or obvious in view of the collective teachings of

Gombrich, Leigh-Spencer, and the article by the Computer Science

Telecommunications Board based on the logic and sound scientific reasoning of one

ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks

and explanations given above, and incorporated herein.

As such, it is respectfully submitted that Appellant appears to view the applied

references in a vacuum without considering the knowledge of average skill in the art.

In reference to the Appellant's arguments that the Gombrich reference teaches two

separate interfaces, it is noted that Gombrich discloses the following:

a system for providing accurate identification of a patient and for items relating to

a patient such as drugs (col. 1 lines 9-17 and col. 2 lines 36-45) comprising:

(a) a housing (col. 4 line 63 to col. 5 line 1-2);

(b) a programmed microprocessor (col. 12 lines 14-66);

(c) an LCD display and keypad for displaying information, wherein the keyboard

and LCD are disposed on the surface of the housing and are connected to the

programmed microprocessor (Fig. 26, col. 4 line 63 to col. 5 line 1-2, col. 5 line 35 to

col. 6 line 11, col. 12 lines 14-66);

(d) interface means, including a port for connection to external systems and I/O

channels such as terminals and a computer system, for communicating data using RF

or infrared signals (Fig. 1, col. 4 line 21 to col. 6 line 11, and col. 12 lines 14-66);

(e) memory associated with a programmed microprocessor within the bar code

reading device housing (col. 12 lines 14-66) to:

(1) receive at the PHPT (also called the bar code reading device) prescription

information through the interface, wherein prescription information includes a

recommended dosage and time to administer drugs (col. 15 line 51 to col. 16 line 17,

col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24);

and

(2) download from memory of the PHPT data via the communications port,

wherein the data includes drug information, such as drugs administered (col. 24 lines

11-36).

Further, the Examiner broadly interpreted the Gombrich reference to provide

input and output of data through a single device, thus reading on an "input/output"

interface. Therefore, the Examiner respectfully submits that Gombrich taken collectively

with Leigh-Spencer, and the article by the Computer Science Telecommunications

Board used in the rejection of claim 14 is a proper rejection, and thus the rejection is

maintained.

III.   With respect to the objection of claims 1, 7, and 14 under 35 U.S.C. 132

(A) With respect to Appellant's argument that the Examiner erroneously rejected claims 1, 7, and 14 as unpatentable under 35 U.S.C. 132, because the material added by amendment was not new matter, the Examiner respectfully submits that the Appellant did not provide in a previous response, a detailed explanation of support for the newly added limitations. The only support the Appellant provided for the newly added limitations was found in the response filed 13 June 2003 and reads as follows: "The new claim 20 asserts previously unclaimed subject matter that is set forth in the specification from page 14, line 18 through page 15, line 4." Therefore, after reviewing Appellant's new arguments in the brief (see pages 26-38), the Examiner respectfully submits that the objection to the specification under 35 USC 132 because the material added by amendment was new matter is hereby withdrawn.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
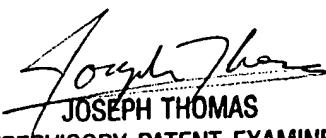
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